



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/691,917

10/23/2003

Ruchika Singhal

1023-234US01

6514

28863

7590

10/12/2006

SHUMAKER & SIEFFERT, P. A.
8425 SEASONS PARKWAY
SUITE 105
ST. PAUL, MN 55125

EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/691,917		SINGHAL ET AL.	
	Examiner		Art Unit	
	Michael Kahelin		3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20040920</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 19-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In regards to claim 19, the claim is unclear because nothing has been set forth to deliver therapy.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 8-10, 12, 13, 16, 18-21, 27-29, 32, 35-40, 43-45 and 48-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Torgerson et al. (US 5,893,883, hereinafter "Torgerson").
5. In regards to claims 1, 19 and 38, Torgerson discloses a device/method that defines an event, monitors therapy delivered during the event (col. 9, line 58), generates therapy information based on the monitored therapy (col. 3, line 26), subsequently

Art Unit: 3762

detects the defined event, and provides therapy according to the therapy information (col. 9, line 66).

6. In regards to claims 2, 20 and 39, defining the event comprises receiving indication of the event from the user via a user interface (col. 9, line 58 and Fig. 5).

7. In regards to claims 3, 21 and 40, the event is an activity or posture (col. 9, line 63).

8. In regards to claim 8, the therapy information is a value of a therapy parameter that controls delivery of therapy (col. 10, line 19).

9. In regards to claims 9, 10, 28, 29, 43, 44 and 45, the recording the value of the parameter comprises recording a change to the parameter subsequent to receipt of the command (Fig. 8; 813 to 806), and the path from 813 to 806 encompasses some "period of time".

10. In regards to claims 12, 13 and 36, the change to the therapy is made via a programming device (Figs. 4 and 5), and the change is amplitude (404 and 406), width (408 and 410) or rate (412).

11. In regards to claims 16 and 32, the event is presented to a clinician as diagnostic data (col. 10, line 52).

12. In regards to claims 18, 37, 48, 49, 51 and 53, a command is given to enter a learning mode by a clinician or patient (813).

13. In regards to claim 27, the processor associates the value and event in memory (col. 10, line 42).

Art Unit: 3762

14. In regards to claims 35, 50, 52 and 54, the therapy comprises managing pain with and implantable neurostimulator (col. 1, line 26).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 11, 30, and 46 are rejected under 35 U.S.C. 102(b) as anticipated by Torgerson or, in the alternative, under 35 U.S.C. 103(a) as obvious over Torgerson in view of Schallhorn (US 6,120,467, hereinafter "Schallhorn"). Torgerson discloses the essential features of the claimed invention, including adjusting the stimulation in response to various activities (col. 9, line 66), which would inherently entail changing the therapy parameters subsequent to detection of the event. Alternatively, Schallhorn

Art Unit: 3762

teaches of adjusting the therapy subsequent to detection of an event (118 and 120) to provide pain therapy that is tailored to a patient's activity. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Schallhorn's invention with a means for adjusting the therapy subsequent to detection of an event to provide pain therapy that is tailored to a patient's activity.

18. Claims 4-7, 17, 22-26, 33, 35-37, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torgerson in view of Schallhorn (US 6,120,467, hereinafter "Schallhorn"). Torgerson discloses the essential features of the claimed invention except for monitoring a sensor to define and detect the event wherein the sensor is a multi-axis accelerometer, and the sensor is monitored over a period of time subsequent to the command; or presenting the event as a marker within a timing diagram.

Schallhorn teaches of an SCS system responsive to patient activity wherein an accelerometer is utilized to determine patient motion (abstract) to eliminate the need for user input to define activities, thus rendering the operation of the device more convenient for the user; monitoring the sensor over a period of time subsequent to the command (col. 3, line 39) to acquire an "average activity" that has less noise than an instantaneous measurement (per the central tendency theorem); and presenting the event as a marker within a timing diagram (Fig. 3B, activity is the "event") to monitor the treatment over time, thus determining efficacy. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Torgerson's invention wherein an accelerometer is utilized to determine patient motion to eliminate the need for user input to define activities, thus rendering the operation of

the device more convenient for the user; monitoring the sensor over a period of time subsequent to the command to acquire an "average activity" that has less noise than an instantaneous measurement (per the central tendency theorem); and presenting the event as a marker within a timing diagram to monitor the treatment over time, thus determining efficacy.

19. In regards to the claimed limitation of utilizing a multi-axis accelerometer, Schallhorn is silent as to the specific type of accelerometer used. However, it is well known in the art to utilize multi-axis accelerometers to acquire a more accurate measure of total acceleration by virtue of measuring in all three dimensions. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Torgerson's modified invention with a multi-axis accelerometer to acquire a more accurate measure of total acceleration by virtue of measuring in all three dimensions.

20. Claims 14, 15, 31, 34, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torgerson in view of Bourgeois (US 5,058,584, hereinafter "Bourgeois"). Torgerson discloses the essential features of the claimed invention including receiving treatment parameters from the user, but does not disclose changing delivery of therapy subsequent to detection of the event based on a parameter and time; or suspending therapy in response to the detection of the event. Bourgeois teaches of changing delivery of therapy subsequent to detection of the event based on a parameter and time (Fig. 4B, 119) to avoid the side-effects associated with unnecessary stimulation; and suspending therapy in response to the detection of the

event (abstract; i.e. activity below the threshold) also to avoid the side-effects associated with unnecessary stimulation. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Torgerson's invention by changing delivery of therapy subsequent to detection of the event based on a parameter and time, and suspending therapy in response to the detection of the event to avoid the side-effects associated with unnecessary stimulation.

Response to Arguments

21. Applicant's arguments with respect to claims 1-54 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment.

Conclusion

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sheldon (US 5,593,431) is one of many teachings of a multi-axis accelerometer in an activity-monitoring stimulator.

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

Art Unit: 3762

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK

MWK
9/29/06

GEORGE R. EVANISKO
PRIMARY EXAMINER
10/5/06